

REMARKS

In the Office Action, Claims 1-36 are rejected under 35 U.S.C. § 112, first paragraph; Claims 1-4, 9-12, 15-19, 22, 23, 26-30, 33, and 34 are rejected under 35 U.S.C. § 102; and Claims 1-36 are rejected under 35 U.S.C. § 103. Claims 1, 15 and 26 have been amended. Applicants believe that the rejections have been overcome in view of the amendments and for the reasons set forth below.

In the Office Action, Claims 1-36 have rejected under 35 U.S.C. §112, first paragraph. Applicants believe that this rejection has been overcome. Of the pending claims at issue, Claims 1, 15 and 26 are the sole independent claims. Each of the claims have been amended to recite a lipid source have an omega 6 to 3 fatty acid ratio. Support for such amendment can be found in the specification on page 8 at lines 20-23 and further in the examples, such as on page 14 at line 1. Applicants have also amended the specification in the paragraph beginning at page 2 on line 27 to make this change as well. Applicants note for the record that the changes to claim 1, 15 and 26 as discussed above were made for clarification purposes to correct an inadvertent error and thus Applicants do not intend to disclaim or narrow any claimed subject matter in view of same. Therefore, Applicants believe that the enablement requirement should be satisfied.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claim 1-4, 9-12, 15-19, 22, 23, 26-30, 33, and 34 are rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 6,200,950 (“Mark”). Applicants believe that this rejection has been overcome as described in detail below.

Of the pending claims at issue, Claims 1, 15, and 26 are the sole and independent claims. Claim 1 recites a method for improving muscle synthesis; Claim 15 recites a method for preventing muscle loss in an individual at risk of same; and Claims 26 recites a method for accelerating muscle mass recovery. As amended, Claim 1 recites, in part, that the lipid source comprises at least 40% by weight of monosaturated fatty acids; Claim 15 recites, in part, administering a therapeutically effective amount of a composition as defined in Claim 15 to an individual at risk of muscle loss; and Claim 26 recites, in part, administering a therapeutically effective amount of a composition to an individual requiring accelerated muscle mass recovery.

Applicants have discovered that the methods and nutritional supplements as claimed are particularly suitable for providing supplemental nutrition to an individual that requires or that

can benefit from increased muscle synthesis. Such an individual can include, for example, the elderly, anorexic patients or those who have an impairment to digest other sources of protein. Due to its components, the supplement is more rapidly digested and therefore the patient is more likely to consume a therapeutically effective amount of the supplement or other food to provide for adequate nutrition. See, Specification, Page 7, lines 11-16.

In contrast, Applicants believe that Mark is distinguishable from the claimed invention for at least a number of reasons. For example, nowhere does Mark disclose or suggest a composition that includes, in part, a lipid source with at least 40% by weight of monosaturated fatty acids wherein the composition can be therapeutically administered to improve muscle protein synthesis as required by Claim 1.

Further, the emphasis of Mark relates to compositions that are designed to address the general nutrition needs of specific class of persons namely, metabolically stress patients. See, Mark, column 6, lines 13-29. In contrast, the claimed methods are directed to improve muscle protein synthesis (Claim 1), to prevent muscle loss in an individual at risk of muscle loss (Claim 15) and to accelerate muscle mass recovery in a individual requiring accelerated muscle mass recovery (Claim 26). Indeed, Mark does not even mention the word "muscle," let alone compositions that can be used for improving muscle protein synthesis, preventing muscle loss or accelerating muscle recovery as claimed. Again, Mark merely suggests that the compositions disclosed therein are purportedly utilized to treat metabolically stressed patients. Moreover, this specific class of patients is defined as "patients who, due to either disorder or condition, are unable to tolerate whole protein diets and need fluid restriction, while at the same time, cannot tolerate elevated protein levels or excess fluid." See, Mark, column 6, lines 13-20. Thus, the class of persons that need such help as improving muscle protein synthesis, preventing muscle loss or accelerating muscle recovery as claimed is a very different class from the seriously ill subjects as disclosed in Mark.

Based on at least these differences, Applicants believe that Mark is clearly distinguishable from the claimed invention. Therefore, Applicant respectfully submit that Mark fails to anticipate the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, Claims 1-36 are rejected under 35 U.S.C. § 103. More specifically, Claims 1-4, 6-12, 15-23 and 26-34 are rejected in view of Mark and further in view of Whitney; Claim 5 is rejected in view of Mark and Whitney and further in view of Ballevre et al, Kawasaki et al. or Etzel; and Claims 13, 14, 24, 25, 35 and 36 are rejected in view of Mark and Whitney and further in view of Cavaliere et al. Applicants believe that the obviousness rejections have been overcome and should be withdrawn.

Of the pending claims at issue, Claims 1, 15 and 26 are the sole independent claims. Foremost, Mark is clearly distinguishable from the claimed invention as defined by Claims 1, 15, and 26 at least based on substantially the same reasons as discussed above. Therefore, Mark on its own is distinguishable from the claimed invention.

Further, Applicants believe that the remaining cited references (i.e., Whitney, Ballevre, Kawasaki and Etzel) together or alone fail to remedy the deficiencies of Mark. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify Mark in view of the remaining cited references to arrive at the claimed invention.

Based on at least these reasons, Applicants believe that the cited art is distinguishable from the claimed invention. Therefore, Applicants respectfully submit that the cited art even if combinable fails to render obvious the claimed invention as required by Claims 1-36.

Accordingly, Applicants respectfully request that the obviousness rejections with the respect to Claims 1-36 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnest solicit reconsideration of the same.

Respectfully submitted,

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